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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 17-X-2006  
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NOT FOR PUBLICATION

**COMMISSION DECISION**

**of 17-X-2006**

**amending the marketing authorisation for "Cetrotide - Cetrorelix (as acetate)", a medicinal product for human use, granted by Decision C(1999)939**

**(Text with EEA relevance)**

**(ONLY THE ENGLISH TEXT IS AUTHENTIC)**

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**(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>1</sup>,

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93<sup>2</sup>, and in particular the third subparagraph of Article 4(5), and the first subparagraph of Article 6(10) thereof,

Having regard to the application(s) submitted by Serono Europe Ltd. on 22 August 2006 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the notification submitted by Serono Europe Ltd. under Article 4(1) of Regulation (EC) No 1085/2003,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>3</sup>, and in particular Article 61(3) thereof,

Having regard to the opinion(s) of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 21 September 2006,

Whereas:

- (1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Cetrotide - Cetrorelix (as acetate)", which is entered in the Community Register of Medicinal Products under No(s)

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<sup>1</sup> OJ L 136, 30.4.2004, p. 1

<sup>2</sup> OJ L 159, 27.6.2003, p. 24.

<sup>3</sup> OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

EU/1/99/100/001-003 and the placing on the market of which was authorised by Decision C(1999)939 of 13 April 1999, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use<sup>4</sup>.

- (2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(1999)939 accordingly.
- (3) The European Medicines Agency acknowledged, between 17 May 2005 and 21 September 2006, the validity of the notification(s) for minor variations of type IA, informing the marketing authorisation holder accordingly, and has prepared a list of the notification(s). The variation(s) took effect from the date of the communication from the European Medicines Agency concerning the validation.
- (4) Serono Europe Ltd. submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the package leaflet, which has (have) not yet been included in Decision C(1999)939 of 13 April 1999.
- (5) The marketing authorisation should be updated, and Decision C(1999)939 amended accordingly.

HAS ADOPTED THIS DECISION:

#### *Article 1*

Decision C(1999)939 is amended as follows:

1) The following list of notifications for minor variations is added to the updated marketing authorisation.

Application number Scope (EU numbers affected)

EMEA/H/C/233/IA/19            5 (IA) (EU/1/99/100/001-003)

2) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number Annex (EU numbers affected)

EMEA/H/C/233/N/18IIIB (EU/1/99/100/001-003)

3) Annex I is replaced by the text set out in Annex I to this Decision;

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<sup>4</sup> OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34).

- 4) Annex II is replaced by the text set out in Annex II to this Decision;
- 5) Annex III is replaced by the text set out in Annex III to this Decision.

*Article 2*

This Decision is addressed to Serono Europe Ltd., 56, Marsh Wall, London E14 9TP, United Kingdom.

Done at Brussels, 17-X-2006

*For the Commission*  
*Heinz ZOUREK*  
*Director-General*